

Appendices

Appendix F: Report of the Advisory Committee on Research on Women's Health, FYs 2007-2008 (excerpt)

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REPORT OF THE ADVISORY
COMMITTEE ON RESEARCH
ON WOMEN'S HEALTH



FISCAL YEARS
2007-2008

OFFICE OF
RESEARCH ON
WOMEN'S HEALTH
&
NIH SUPPORT
FOR RESEARCH ON
WOMEN'S HEALTH ISSUES

Preface

The Advisory Committee on Research on Women's Health (ACRWH), in concert with the Office of Research on Women's Health (ORWH) and the Coordinating Committee on Research on Women's Health (CCRWH), submits to the Director of the National Institutes of Health (NIH) this Biennial Report for fiscal years (FYs) 2007 and 2008. The report describes the comprehensive and coordinated efforts of the ORWH and the NIH Institutes, Centers (ICs), and Offices to address women's health issues through research and related activities in accordance with the NIH Revitalization Act of 1993. The information in this Biennial Report was prepared by the ORWH and by each of the NIH ICs and Offices to highlight significant research studies and other achievements and initiatives that have contributed to an increased knowledge of women's health. Using criteria supplied by the NIH Office of Financial Management (OFM) and the U.S. Department of Health and Human Services Office on Women's Health, and based on budget data provided by NIH ICs, this report also contains information on NIH budget allocations for women's health research during FY 2007 and FY 2008. In addition, the report contains information obtained from the NIH ICs and Offices documenting the inclusion of women and minorities in NIH-funded clinical research during the same time period.

The ACRWH has reviewed the information contained herein and believes that this Biennial Report accurately reflects the breadth and depth of research and related activities through which the NIH, in FY 2007 and FY 2008, has fulfilled its mandate from the U.S. Congress to address women's health issues and women's inclusion in research.

The ACRWH acknowledges the valuable contributions to this report of the CCRWH, which is made up of the directors of each of the ICs and Offices or their designated representatives. We are also grateful to the many NIH staff members who prepared and reviewed the reports of their ICs or Offices. We appreciate the work of the NIH Tracking and Inclusion Committee in preparing information on the inclusion of women and minorities in NIH-funded research and the work of the NIH OFM in collecting and tabulating the budgetary data published in this report.

Finally, the ACRWH wishes to acknowledge the work of ORWH staff. This Biennial Report reflects the achievements of the ORWH in fulfilling all aspects of its core mission in strengthening and enhancing research related to diseases and conditions that affect women; ensuring the appropriate representation of women in NIH research; supporting the advancement of women in biomedical careers; and building programs to ensure the development of a cadre of researchers, both women and men, in the field of interdisciplinary women's health research.

(For a full listing of ACRWH members for FY 2009, please see pages iv–vi.)

Introduction to the Biennial Report

As directed in the National Institutes of Health (NIH) Revitalization Act of 1993,¹ the Advisory Committee on Research on Women's Health (ACRWH) submits to the NIH Director a report describing the activities of the Committee and its findings related to the mandates and funding for women's health. This report includes coordinated efforts of the NIH Institutes, Centers (ICs), and Offices to address women's health issues through research and related activities. As the 20th anniversary of the establishment of the Office of Research on Women's Health (ORWH) approaches, this FY 2007–2008 Biennial Report bears witness to the phenomenal growth in women's health research and related programs that has occurred since the formation of the Office in 1990. This report reflects major FY 2007–2008 ORWH research programs, initiatives, and activities, as well as highlights that were reported through the Coordinating Committee on Research on Women's Health (CCRWH) from the NIH ICs and Offices. This report is not a comprehensive listing of all NIH research on women's health, which would necessarily be encyclopedic; however, the report does serve to summarize, under a single cover, examples of the wealth of NIH advances in women's health research. This Biennial Report also provides information on and analysis of support for women's health research and related activities. During FY 2007–2008, NIH spent approximately \$3.5 billion per year on research specifically related to women's health and approximately \$23 billion on research relevant to both women and men.

The Biennial Report is divided into two major parts. Part One is based on ORWH programs and describes ORWH scientific, interdisciplinary, research, career development, and research dissemination and outreach programs. Data are also reported on the inclusion of women and minorities in NIH-funded clinical research as provided from the Office of Extramural Research. Many ORWH programs reflect the Office's roles in coordinating trans-NIH activities. Most ORWH programs are conducted in collaboration with NIH ICs and Offices. Other ORWH activities are conducted in collaboration with Federal agencies and/or with public and private partners. Part Two of the Biennial Report provides the individual reports on women's health research from 20 NIH Institutes, 4 Centers, and 7 Offices, which include highlights of some of their most promising research programs.

Office of Research on Women's Health

Information about ORWH programs is organized into six sections covering the following areas: ORWH Research; ORWH Interdisciplinary Research and Career Development Programs; ORWH Biomedical Career Development Activities; ORWH Research Dissemination and Outreach; Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research; and NIH Budget for Women's Health Research.

Section I describes FY 2007–2008 NIH women's health research priorities, developed in coordination with the CCRWH and reviewed by the ACRWH. It also provides a table of ORWH-funded projects grouped by diseases and conditions. It also provides examples of special ORWH research initiatives in FY 2007–2008 and highlights of ORWH-cofunded research projects and research workshops and conferences. A strategic planning effort, begun in 2008, is described in Section I. The effort, which will update the 1999 *Agenda for Research on Women's Health for the 21st Century*, is currently ongoing. It is anticipated that the updated research agenda will be completed in time for the 20th anniversary of the founding of ORWH in September 2010.

The *Agenda for Research on Women's Health for the 21st Century* recognized that women's health research is an inherently broad interdisciplinary field of endeavor, encompassing a full range of science. Since 1999, ORWH has been working to provide institutional support for interdisciplinary research and interdisciplinary research career development. Section II highlights major ORWH efforts to catalyze interdisciplinary women's health research and career development through two programs:

¹ The NIH Revitalization Act of 1993, P.L. 103-43, 107, Stat. 22 [codified at 42 U.S.C. 289(a)(1)] [Sec. 486(287d)(d)].

the Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health, and the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Institutional Mentored Career Development Program. Section II also describes ORWH efforts to catalyze NIH interdisciplinary research and IC collaboration to advance understanding of a specific multifactorial condition predominantly affecting women, namely chronic fatigue syndrome.

Since its inception in 1990, the mandate of ORWH has included women's career development and the development of women's health researchers. The BIRCWH program is a major example of a highly successful mentored career development program that was developed and implemented by ORWH in 1999. Section III provides information on a number of other programs through which ORWH works to promote women's biomedical career development and the development of careers in research on women's health and sex/gender factors. Section III reports on the collaborative efforts of ORWH and the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) in supporting the Women's Reproductive Health Research Career Development program, and on the ORWH-initiated trans-NIH Reentry into Biomedical and Behavioral Careers Research Supplement Program.

Section III describes the activities of the NIH Director's Working Group on Women in Biomedical Careers to provide an NIH response to the challenges to Federal agencies posed in the 2007 National Academy of Sciences report, *Beyond Bias and Barriers: Fulfilling the Potential of Women in Academic Science and Engineering*. Section III also highlights FY 2007–2008 ORWH/NIH Intramural Women's Health Research programs, ranging from a summer research program for high school students interested in science to negotiation skills for tenure-track women scientists. The section ends with a summary of a wide range of other ORWH activities to promote the career development of women, some of which involve partnering with professional societies.

Section IV on research dissemination and outreach provides information on new ORWH Internet-based health information initiatives, including a collaborative effort with the NIH National Library of Medicine to create an online resource for information on women's health research; a Web-based course cosponsored with the Food and Drug Administration (FDA) on *The Science of Sex and Gender in Human Health*; and a multimedia approach to communicate advances being made from past and current women's health research. ORWH strives to ensure that the information generated from the NIH investment in research on women's health informs future research efforts and improves women's health care. Thus, outreach to the largest possible population of clinicians and researchers, women, healthcare providers, and others interested in women's health is a very important part of its mandate. Section IV describes ORWH outreach activities, including the Women's Health Seminar series and the Vulvodysplasia Awareness campaign.

Section V details NIH efforts to monitor the inclusion of women and minorities in NIH-funded clinical research, including data by ICs as well as NIH aggregate figures. Section VI provides information on NIH expenditures on women's health research, including a breakdown of expenditures by disease category and other major categories of interest (e.g., aging research).

NIH IC Support for Research on Women's Health

Part Two of the Biennial Report is composed of individual reports from each of 20 NIH Institutes, 4 Centers, and 7 Offices located within the Office of the Director, NIH. These IC and Office reports summarize their major initiatives and activities and provide highlights of their funded research related to women's health and sex/gender research, consistent with their specific missions.

You are invited to read this in-depth report to become acquainted with the tremendous advances in women's health research that have taken place during this 2-year period and to appreciate the promise for even greater advances in the future, not just for women's health, but also for men's health and for careers in women's health research for both men and women.

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Office of Research on Women's Health (ORWH)

INTRODUCTION TO ORWH PROGRAMS

In 1983, the Assistant Secretary for Health, Dr. Edward N. Brandt, established the U.S. Public Health Service Task Force on Women's Health Issues, in recognition of the paucity of data related to women's health. The Task Force produced a 1985 report, *Women's Health: Report of the Public Health Service Task Force on Women's Health Issues, Volume I*.² The report delineated a series of criteria for differentiating a health problem, condition, or disease as a woman's issue. The criteria included the following:

- Diseases or conditions unique to women or some subgroup of women;
- Diseases or conditions more prevalent in women or some subgroup of women;
- Diseases or conditions more serious in women or some subgroup of women;
- Diseases or conditions for which risk factors are different for women or some subgroup of women; or
- Diseases or conditions for which interventions are different in women or some subgroup of women.

The report also recommended that "biomedical and behavioral research should be expanded to ensure emphasis on conditions and diseases unique to, or more prevalent in, women in all age groups."

Following the issuance of the Task Force report, the National Institutes of Health (NIH) established a policy for the inclusion of women in clinical research. This policy, which urged the inclusion of women, was first published in the *NIH Guide to Grants and Contracts* in 1987.³ Later that year, minority scientists and other researchers at NIH recognized the need to address the inclusion of minority populations. As a result, a subsequent version of the NIH Guide published for the first time a policy encouraging the inclusion of minorities in clinical studies.⁴

In 1990, the Congressional Caucus for Women's Issues requested that the General Accounting Office (GAO), now known as the Government Accountability Office, conduct an investigation into the implementation of the guidelines for the inclusion of women by NIH. This report, included in congressional testimony, indicated that the implementation of the policy for the inclusion of women was slow and not well communicated, that gender analysis was not being performed routinely, and that the impact of this policy could not be determined.⁵ The GAO testimony also indicated that there were differences in the implementation of the policy recommending the inclusion of minorities, and that not all Institutes and Centers (ICs) factored adherence to these policies into scientific merit review. GAO findings concerning the lack of consistent implementation of policies for inclusion of women in NIH clinical trials led NIH to establish the ORWH within the Office of the

²U.S. Public Health Service. Women's health: Report of the Public Health Service Task Force on women's health issues. *Public Health Reports* 100(1):74-106, 1985.

³Division of Research Grants. Inclusion of women in study populations. *NIH Guide to Grants and Contracts* 16(3):2, 1987.

⁴Division of Research Grants. Inclusion of minorities in study populations. *NIH Guide to Grants and Contracts* 16(32):3-4, 1987.

⁵National Institutes of Health: *Problems in Implementing Policy on Women Study Populations* (GAO/T-HRD-90-38, 1990). Washington, DC: U.S. Government Accountability Office.

NIH Director in September 1990. Since its establishment, ORWH has served as the focal point for women's health research at NIH. The responsibilities of the Director, ORWH, include the following:

- (1) Advises the NIH Director and staff on matters relating to research on women's health;
- (2) Strengthens and enhances research related to diseases, disorders, and conditions that affect women;
- (3) Ensures that research conducted and supported by NIH adequately addresses issues regarding women's health;
- (4) Ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH;
- (5) Develops opportunities for and supports recruitment, retention, reentry, and advancement of women in biomedical careers; and
- (6) Supports research on women's health issues. ORWH works in partnership with the NIH Institutes and Centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

ORWH was established in statute in the NIH Revitalization Act of 1993.⁶ An Advisory Committee on Research on Women's Health (ACRWH), composed of non-Federal members, was also statutorily mandated in the Revitalization Act as a mechanism for eliciting advice and recommendations on priority issues affecting women's health research. This Committee provides leadership to ORWH by advising the ORWH Director on appropriate research activities in women's health. ACRWH members are chosen from among health practitioners, advocates, research scientists, educators, and other professionals. Committee members are actively involved in reviewing and advising on matters related to research priorities, the women's health research portfolio for NIH, career development, inclusion of women and minorities in NIH-funded clinical research, and other ORWH or NIH programs related to women's health.

ORWH also benefits from the advice of a Coordinating Committee on Research on Women's Health (CCRWH). The CCRWH was also established in statute in the 1993 NIH Revitalization Act and is composed of Institute and Center Directors or their designees as a direct liaison for ORWH with NIH ICs. Both the ACRWH and the CCRWH provide valuable guidance, collaboration, and support for activities of ORWH in women's health research, career programs, and outreach efforts.

ORWH programs and efforts have expanded in breadth and depth over the years. The research funded or cofunded by ORWH is based on collaborative efforts with the ICs and supports peer-reviewed, science-driven initiatives. These collaborations are benefiting the health of all Americans across the lifespan, men as well as women, and all racial and ethnic groups.

⁶The NIH Revitalization Act of 1993, P.L. 103-43, 107, Stat. 22 [codified at 42 U.S.C. 289(a)(1)] [Sec. 486(287d)(d)].